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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/788,866 | 02/27/2004 | Fred J. Molz | 4002-3434 / PC834.00 | 7218 |
| 30565 | 7590 | 05/17/2007 | EXAMINER | |
| WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP | | | REIMERS, ANNETTE R | |
| 111 MONUMENT CIRCLE, SUITE 3700 | | | ART UNIT | PAPER NUMBER |
| INDIANAPOLIS, IN 46204-5137 | | | 3733 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/788,866 | MOLZ ET AL. | |
| | Examiner | Art Unit | |
| | Annette R. Reimers | 3733 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 February 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) 8,12,17 and 38-58 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-7,9-11,13-16 and 18-37 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 27 February 2004 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1-5, 10, 14-15, 18-26, 28-30, 32-34 and 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Dunn et al. (US Patent Number 4,731,084).

Dunn et al. disclose a surgical tether for orthopedic treatment to secure to two adjacent bone portions, the tether comprising a single fiber elastomeric, flexible cord, e.g. 30, having a tensile strength sufficient to maintain a desired distance or orientation of the two bone portions; a flexible first sheath, e.g. 20, substantially encasing the cord, the first sheath comprising a plurality of fibers and providing an abrasion resistant coating to the cord; a radiopaque element comprising barium sulfate; and a second sheath, e.g. 40, the second sheath substantially encasing the first sheath, wherein the cord is slidably received within the second outer cord, wherein the cord is elongate and defines a longitudinal axis and wherein the cord is free to move longitudinally with respect to the first sheath, wherein the first and second sheaths are frictionally engaged with each other, wherein the second sheath is not fixedly secured to either the cord or the first sheath, wherein the radiopaque element comprises one or more radiopaque filaments spirally wound around at least one of the cord, the first sheath or the second

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sheath, wherein the tether is attached to a plurality of bone portions, wherein the two bone portions include a first and second vertebrae, wherein the two bone portions include an articulating joint, wherein the cord is composed of a polymeric material selected from the group consisting of: polyethylene, ultra high molecular weight polyethylene, polypropylene, fluoropolymers, polytetrafluoroethylene, polyamides, polyethylene terephthalate, polyesters, polyaramid, silicon rubbers, polyurethane, polyvinylchloride, wherein the first sheath is composed of a material different from the cord, wherein the first sheath is composed of a material selected from the group consisting of: polyethylene, polypropylene, fluoropolymers, polytetrafluoroethylene, polyamides, polyethylene terephthalate, polyesters, polyaramid, silicon rubbers, polyurethane, polyvinylchloride, wherein the cord and first sheath are composed of a non-biodegradable material, wherein the radiopaque element is composed of a biocompatible metallic fiber, wherein the radiopaque element is composed of a material selected from the group consisting of: nitinol, titanium, titanium-vanadium-aluminum alloy, cobalt-chromium alloy, cobalt-chromium-molybdenum alloy, cobalt-nickel-chromium-molybdenum alloy, stainless steel, tantalum, niobium, hafnium, tungsten, gold, silver, platinum, and iridium metals, alloys, and mixtures thereof. A first bone fastener and a second bone fastener to secure the tether to the two bone portions, wherein the first and second bone fasteners secure the cord to the first and second bone portions, wherein the second sheath is not secured to the two or more bone portions (see figures 1-5, column 5, lines 5-19 and column 6, lines 37-39).

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With regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Dunn et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6-7, 9-11, 13-16, 18 23, 29, 31 and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poirier et al. (US Pat 2,737,075) in view of Dunn et al. (US Patent Number 4,731,084).

Poirier et al. disclose a surgical tether for orthopedic treatment to secure to two adjacent bone portions, the tether comprising a braided plurality fiber elastomeric, flexible cord, e.g. 12, having a tensile strength sufficient to maintain a desired distance or orientation of the two bone portions; a flexible first sheath, e.g. 16, substantially

encasing the cord, the first sheath comprising a plurality of fibers and providing an abrasion resistant coating to the cord; and a second sheath, e.g. 20, the second sheath comprising a plurality of braided fibers substantially encases the first sheath, wherein the cord is slidably received within the second outer cord, wherein the cord is elongate and defines a longitudinal axis and wherein the cord is free to move longitudinally with respect to the first sheath, wherein the first and second sheaths are frictionally engaged with each other, wherein second sheath is not fixedly secured to either the cord or the first sheath (see figure 1 and column 2, lines 14-19).

Poirier et al. disclose the claimed invention except for a radiopaque element and first and second bone fasteners securing the cord to the first and second bone portions. Dunn et al. disclose a tether containing a radiopaque element and the use of bone fasteners and teach the use of a radiopaque element to radiographically visualize the prosthetic ligament and the use of fasteners to connect the prosthetic ligament to bone (see column 3, lines 9-12 and 25-27). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Poirier et al. with a radiopaque element and first and second bone fasteners securing the cord to the first and second bone portions., in view of Dunn et al., to radiographically visualize the prosthetic ligament and to connect the prosthetic ligament to bone. In addition, any of the sheaths and the core can contain the radiopaque element and the radiopaque element can comprise a plurality of fibers, from either the core or the sheaths or e.g. 26 of Poirier et al. Furthermore, if the cord of Poirier et al. was secured by first and second bone fasteners, the first sheath, i.e. 16, would not be secured to the two bone portions.

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Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al. (US Patent Number 4,731,084) in view of Hlavacek et al. (US Patent Number 4,792,336).

Dunn et al. disclose the claimed invention except the cord and the first sheath being biodegradable. Hlavacek et al. disclose a biodegradable tether and the use of a biodegradable material to permit adequate time for new tissue ingrowth or revascularization (see column 4, lines 38-39). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Dunn et al. with the cord and the first sheath being biodegradable, in view of Hlavacek et al. to permit adequate time for new tissue ingrowth or revascularization.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al. (US Patent Number 4,731,084).

Dunn et al. disclose the claimed invention except the radiopaque element exhibits an effective duration in vivo of between about one month and about 5 years. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Dunn et al. with the radiopaque element exhibits an effective duration in vivo of between about one month and about 5 years, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed February 20, 2007 have been fully considered but they are not persuasive. Examiner respectfully disagrees with applicant regarding the Dunn et al. reference. Dunn et al. disclose a cord, e.g. 30, having a tensile strength sufficient to maintain a desired distance or orientation of two bone portions and the first sheath e.g. 20, provides an abrasion resistant coating to the cord (see abstract, column 2, lines 20-47, column 6, lines 37-68 and column 7, lines 1-5). Furthermore, a recitation of the intended use of the claimed invention, e.g. having a tensile strength sufficient to maintain a desired distance or orientation of two bone portions, must result in a structural difference between the claimed invention and the prior art to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In addition, it is noted that the features upon which applicant relies (i.e., the present specification, the material of a coating or sheath can be selected for abrasion resistance, or other factors can be introduced so that the resistance to abrasion is increased) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding the Poirier et al. reference failing to disclose a surgical tether for orthopedic treatment, the recitation "A surgical tether for orthopedic treatment" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the

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purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Regarding Poirier et al. in view of Dunn et al., as stated above, Poirier et al. disclose a surgical tether for orthopedic treatment to secure to two adjacent bone portions, the tether comprising a braided plurality fiber elastomeric, flexible cord, e.g. 12, having a tensile strength sufficient to maintain a desired distance or orientation of the two bone portions; a flexible first sheath, e.g. 16, substantially encasing the cord, the first sheath comprising a plurality of fibers and providing an abrasion resistant coating to the cord; and a second sheath, e.g. 20, the second sheath comprising a plurality of braided fibers substantially encases the first sheath, wherein the cord is slidably received within the second outer cord, wherein the cord is elongate and defines a longitudinal axis and wherein the cord is free to move longitudinally with respect to the first sheath, wherein the first and second sheaths are frictionally engaged with each other, wherein second sheath is not fixedly secured to either the cord or the first sheath (see figure 1 and column 2, lines 14-19).

Poirier et al. disclose the claimed invention except for a radiopaque element and first and second bone fasteners securing the cord to the first and second bone portions. Dunn et al. disclose a tether containing a radiopaque element and the use of bone fasteners and teach the use of a radiopaque element to radiographically visualize the prosthetic ligament and the use of fasteners to connect the prosthetic ligament to bone

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(see column 3, lines 9-12 and 25-27). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Poirier et al. with a radiopaque element and first and second bone fasteners securing the cord to the first and second bone portions., in view of Dunn et al., to radiographically visualize the prosthetic ligament and to connect the prosthetic ligament to bone. In addition, any of the sheaths and the core can contain the radiopaque element and the radiopaque element can comprise a plurality of fibers, from either the core or the sheaths or e.g. 26 of Poirier et al. Furthermore, if the cord of Poirier et al. was secured by first and second bone fasteners, the first sheath, i.e. 16, would not be secured to the two bone portions.

Regarding Dunn et al. in view of Hlavacek et al., in claim 27, applicant is claiming "the cord and first sheath are composed of a biodegradable material," which is equivalent to "the cord and first sheath comprising a biodegradable material." Applicant is not claiming "the cord and first sheath consisting of a biodegradable material." Thus, the cord and first sheath can contain materials in addition to biodegradable material, e.g. non-biodegradable material: Hlavacek et al. clearly discloses the use of biodegradable and non-biodegradable materials in combination (see column 1, lines 7-47, and column 4, lines 22-54). Thus, it would have been obvious to one skilled in the art at the time the invention was made to construct the device of Dunn et al. according to the teachings of Hlavacek et al.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR



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SUPERVISORY PATENT EXAMINER